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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,666	02/08/2002	Gyanendra Kumar	13172.0015U1	3290
23859 7590 01/24/2007 NEEDLE & ROSENBERG, P.C.			EXAMINER	
SUITE 1000	·		CHUNDURU, SURYAPRABHA	
999 PEACHTREE STREET ATLANTA, GA 30309-3915			ART UNIT	PAPER NUMBER
		•	1637	
			•	*
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		01/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/072,666	KUMAR ET AL.				
Office Action Summary	Examiner	Art Unit				
	Suryaprabha Chunduru	1637				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 13 December 2006.  2a)□ This action is FINAL. 2b)⊠ This action is non-final.  3)□ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
<ul> <li>4)  Claim(s) 1-138 is/are pending in the application.</li> <li>4a) Of the above claim(s) 137 and 138 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-136 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
9) ☐ The specification is objected to by the Examiner.  10) ☐ The drawing(s) filed on 13 December 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate				

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2006 has been entered.

### Status of the Application

2. The action is in response to the RCE filed on December 13, 2006. Claims 1-136 are pending. Claims 137-138 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive for the reasons that follow.

#### Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-136 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6, 531, 283 in view of Baner et al. (Nucleic Acids Res., Vol. 26 922), page 5073-5078, 1998).

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An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the patent ('283) disclose and encompasses the instant method wherein the method in the patent comprises (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes (see column 41, lines 33-55); (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a singlestranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers (see column 41, lines 56-67); (d) incubating the rolling circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see column 42, lines 32-39). However the method in the patent

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('283) did not specifically disclose a decoupling step to dissociate amplification target circle associated with analytes form specific binding molecule.

Baner et al. teach a method signal amplification of padlock probes by rolling circle replication, wherein Baner et al. teach that the method utilizes circularizing oligonucleotide probes or padlock probes in rolling circle amplification to enhance signal amplification (see page 5075, col. 1, paragraph 1 under results section), wherein Baner et al. disclose that the circularaized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with a step of decoupling amplification target circle as taught by Baner et al, to develop a sensitive method for the detection of multiple analyte(s) because Baner et al. explicitly taught the use of padlock probes in rolling circle amplification, and circularaized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3). Thus an ordinary skill in the art would have a reasonable expectation of success that the modification of the method taught by Kingsmore et al.

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grounds of rejections.

in a manner as taught by Baner et al. would result in an enhanced signal amplification for detecting one or more analytes and such modification of the method is considered as obvious over cited prior art.

Therefore the instant claims are rejected under obviousness-type of double patenting.

\*Response to arguments:\*

- 4. With regard to the objection to the drawings, Applicants' arguments and amendment to the drawings are fully considered and the objection is withdrawn herein in view of the amendment.
- 5. With regard to the rejection of claims 1-11, 23-24, 27-65, 70-102, 107-136 under 35 USC 103(a) as obvious over Lizardi et al. in view of Abarzua, applicants' arguments and amendment are fully considered and the rejection is withdrawn herein in view of the amendment and new
- 6. With regard to the rejection of claims 1-136 under 35 USC 103(a) as obvious over Kingsmore et al. in view of Abarzua, applicants' arguments and amendment are fully considered and the rejection is withdrawn herein in view of the amendment and new grounds of rejections.
- 7. With regard to the rejection of claims 1-136 under obviousness type double patenting, applicants' arguments and amendment are fully considered and the rejection is withdrawn herein in view of the amendment and new grounds of rejections.

#### Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru Primary Examiner Art Unit 1637

SURYAPRABHA CHUNDURU //19/0